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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,994	08/27/2003	Timothy J. Miller	62,589A	4366

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,994	MILLER ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *11-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *111805,82304, 22304*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1) Acknowledgment is made of Applicants' amendment filed 06/19/06. With this, Applicant has amended the specification and the claims.

Election

2) Acknowledgment is made of Applicant's election filed 06/19/06 in response to the lack of unity requirement mailed 05/18/06. Applicants have elected invention I, claims 1-10, without traverse. The invention grouping set forth therein was inadvertently identified as a lack of unity as opposed to a restriction requirement under 35 U.S.C. § 121. The Examiner regrets this inadvertent error. However, the grouping of claims 1-20 under three different inventions as set forth therein and the rejoinder provisions of MPEP 821.04 as set forth therein are still applicable.

Status of Claims

3) Claim 1 has been amended via the amendment filed 06/19/06.

Claims 1-20 are pending.

Claims 11-20 are withdrawn from consideration as being directed to non-elected inventions or species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-10 are under examination. A First Action on the Merits is issued for these claims.

Information Disclosure Statements

4) Acknowledgment is made of Applicants' Information Disclosure Statements filed 11/18/05, 08/23/04 and 02/23/04. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

5) The instant application claims priority to the provisional application 60/406,359 filed 08/27/2002.

Specification

6) The specification of the instant application is objected to for the following reason:

The use of the trademark in the instant specification has been noted. For example, see

section [0046]: 'Triton X-100'; section [0049]: 'Tween 20'; section [0053]: 'glutamax-1'; and section [0065]: 'Tween 80' and 'Span 80'. The recitation should be capitalized wherever it appears or be accompanied by the generic terminology. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

Rejection(s) under 35 U.S.C. § 101

7) 35 U.S.C. § 101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

8) Claim 1 and those dependent therefrom are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1, as written, does not sufficiently distinguish over an LT-producing *E. coli* as it exists naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980)*. The claim(s) should be amended to indicate the hand of the inventor, e.g., by insertion of --an isolated-- or --a purified-- native *E. coli* heat-labile toxin if support for such a limitation existed in the specification. See MPEP 2105.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

9) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

10) Claims 3, 6, 7, 9 and 10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 6, 7, 9 and 10 have improper antecedent basis in the limitation: 'the

adjuvant'. Instant claims depend directly or indirectly from claim 1, which does not include the limitation of an adjuvant.

(b) Claim 3 is vague and indefinite in the limitation 'derived', because it is unclear what is encompassed in this limitation. Does the process of 'deriving' encompass: extraction, isolation, recombinant production, separation, purification, modification, or expression on cell surface? For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the limitation 'derived from the group consisting of' with the limitation --from--.

Rejection(s) under 35 U.S.C. § 102

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> **(e)** the invention was described in-
> **(1)** an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent.

12) Claims 1 and 6 are rejected under 35 U.S.C § 102(b) as being anticipated by Ruedl *et al.* (*Vaccine* 14: 792-798, 1996).

Ruedl *et al.* taught a composition comprising a native *E. coli* heat-labile toxin (LT). The limitation 'for use in vaccinating a bird' represents the intended use of the claimed product and therefore has no patentable weight.

Claims 1 and 6 are anticipated by Ruedl *et al.*

13) Claims 1, 6 and 7 are rejected under 35 U.S.C § 102(e)(1) as being anticipated by Mason *et al.* (US 2003/0176653 A1).

Mason *et al.* disclosed a composition comprising native *E. coli* heat-labile toxin (LT) for use in vaccination or oral vaccination of fowls including chicks, ducks and geese. Fusion proteins of said LT are also taught. The oral administration of LT is accompanied by a protein carrier. A transgenic plant, such as a potato tuber expressing LT, is fed to chicks in order to elicit an immune response. Transgenic plants expressing both the *E. coli* LT holotoxin and a heterologous viral antigen for use in the treatment or prevention of a specific disease or infection are taught. See

sections [0134] through [0146]; [0124] through [0131]; and [0234]; and Examples 21.

Claims 1, 6 and 7 are anticipated by Mason *et al.*

Rejection(s) under 35 U.S.C. § 103

14) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

15) Claims 2-5 and 8-10 are rejected under 35 U.S.C § 103(a) as being unpatentable over Mason *et al.* (US 2003/0176653 A1) as applied to claim 1 above and further in view of Qin *et al.* (CN 1333370 A) and Huang *et al.* (*FASEB J.* 13, 4 part 1: p. A290, 12 March 1999).

The teachings of Mason *et al.* are explained above which do not expressly identify the heterologous viral antigen expressed along with the *E. coli* LT holotoxin to be a immunoprotective viral antigen effective in a bird.

However, expression of an immunoprotective antigen from a fowl virus, such as, the HA antigen of fowl Newcastle disease, or the HA antigenic protein from avian influenza virus, in a transgenic plant was known in the art at the time of the invention. For example, Qin *et al.* taught a composition or a feed comprising a recombinant HA protein of the fowl Newcastle disease virus wherein the protein is produced in a transgenic plant (see abstract).

Similarly, Huang *et al.* taught an oral vaccine for use in poultry comprising recombinant HA antigenic protein of the viral envelope from an avian influenza virus strain produced in a transgenic

plant (see abstract).

Given that the expressions of both the *E. coli* LT holotoxin and the hemagglutinin HA protein of the fowl Newcastle disease or avian influenza hemagglutinin protein in a transgenic plant were known in the art at the time of the invention as taught by Mason *et al.*, Qin *et al.* and Huang *et al.*, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to express the *E. coli* LT holotoxin and the HA protein of the fowl Newcastle disease in a single transgenic plant by modifying Mason's transgenic plant or transgenic potato tuber expressing the *E. coli* LT holotoxin and a heterologous viral antigen to express specifically Qin's HA protein of the fowl Newcastle disease virus instead of the generic heterologous viral antigen to produce the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of advantageously using the resultant transgenic plant or transgenic potato tuber in the treatment or prevention of the specific fowl Newcastle disease or infection in addition to inducing an immune response in fowls or chicks against *E. coli* heat-labile toxin (LT).

Claims 2-5 and 8-10 are *prima facie* obvious over the prior art of record.

Remarks

16) Claims 1-10 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the Office' Central Rightfax number 571-273-8300 via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to

Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Acting supervisor, Albert Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2006

S. DEVI, PH.D.
PRIMARY EXAMINER